Hydratome RX 44 Sphincterotome

Boston Scientific

Group 1

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ASSIGNMENT 1 (NO REGRADE) 3

1. STATEMENT OF CLINICAL PROBLEM 3
2. DESCRIPTION OF CURRENT PRACTICES 4
3. PROBLEM STATEMENT 7
4. NEED STATEMENT 8
5. PRELIMINARY DESIGN CONCEPTS 9

ASSIGNMENT 2 (NO REGRADE) 13

6. STATEMENT OF INTENDED USE 13
7. STATEMENT OF INDICATION OF USE 13
8. FUNCTIONAL & PERFORMANCE SPECIFICATIONS 13
9. TEST PLAN 14
10. PRODUCT DESIGN CONCEPT 15

ASSIGNMENT 3 18

11. INTELLECTUAL PROPERTY REVIEW 18
12. REGULATORY CLASSIFICATION 19
13. REGULATORY NOTIFICATION / APPROVAL 19
14. FMEA 22
15. PRECLINICAL AND HUMAN STUDY PLAN 24
16. STANDARDS AND GUIDELINES 24

APPENDIX 26

A. HANDLE 26
B. SLIDER 27
C. CONTRAST AGENT INJECTION SITE 28
D. CONNECTOR 29
E. CUTTING WIRE INJECTION SITE 30
F. CANNULA 31

REFERENCES 32

Assignment 1 (No Regrade)

1. Statement of Clinical Problem

Normal functioning of the bile ducts, pancreas, and gallbladder promotes healthy digestion through the release of hydrolytic enzymes and bile to breakdown organic materials. Malfunction of this system often begins with improper flow of the powerful digestive solutions through the ducts that lead to the intestines. Often this is a result of narrowing ducts or stenosis of the valve leading to the lumen of the digestive tract.[1] This improper flow of bile and pancreatic juices can cause many secondary problems including gallstones and pancreatitis. To repair this dysfunction, a technique called endoscopic retrograde sphincterotomy (ERS) is used to cut the diseased valve to provide access to the ducts in order to remove gallstones, insert a stent in the duct, or otherwise treat the underlying cause of the disease.[1]

The tools necessary for ERS are threaded through an endoscope to reach the ducts of the pancreas and gallbladder. The endoscope is inserted in the mouth, down the pharynx and esophagus, through the stomach and pylorum, and into the duodenum. The ampulla of Vater is the opening of the common bile duct and pancreatic duct, which controls release of bile for fat digestion and pancreatic juice for the breakdown of carbohydrates, lipids, nucleic acids, and protein respectively. The release of these solutions is controlled by the sphincter of Oddi, a smooth muscular valve.[2] When the end of the endoscope has reached the sphincter of Oddi, a cannula is threaded through the scope and releases fluorescent dye used to detect blockages and lesions in the area. After releasing the dye, the cannula is removed and a cutting tool is inserted. Using the camera on the endoscope as a guide, the cutting device – the spincterotome – cuts through the sphincter of Oddi for access into the ducts. Repair of the ducts or removal of lesions can then be performed. ERS is performed in over 150,000 patients per year to treat these

disorders.[3] Upwards of 1.55 million patients have some form of biliary tract obstruction, which may cause many resounding effects through the biliary system.[5]

General obstruction of the common bile duct and pancreas causes buildup of bile and pancreatic juices in the ducts. Reported associated effects of this include jaundice, itching, pain in the upper right side of abdomen, nausea, vomiting, weight loss, and fever.[4] Obstruction of the biliary ducts may be secondary to gallstones, malignancy, infection, pancreatitis, and biliary cirrhosis, while the disease itself may in turn cause the formation of gallstones. As the duct is obstructed, bilirubin present in the bile accumulates in the tissues of the body and causes the jaundice experienced by patients.[5]

Cause of the biliary obstruction dictates the specific demographics of the disease. Gallstones are the most common cause of biliary duct obstruction and thus are most pertinent in the discussion of the epidemiology of the disease. Persons of Hispanic, Northern European, and Native American descent are at a particularly higher risk for developing biliary obstruction. Women are much more likely to develop biliary disease than men, particularly due to the much higher risk of developing gallstones over the course of a lifetime (35% for women VS 20% for men).[5] Risks of biliary disease increases with age, especially when an individual is past age 40.[6]

2. Description of Current Practices

Malfunctions in the biliary ducts are often difficult to diagnose. The bile duct is on average 4.1 mm wide and 7 mm long. As such, it is difficult to image the area and even more difficult to conclude whether the duct is functioning correctly. To diagnose the disease there are three main options. The first is magnetic resonance imaging (MRI), which noninvasively observes the duct. This approach enables physicians to structurally examine the duct in a process known as magnetic resonance cholangiopancreatography (MRCP).[7] This technique is particularly useful in observing cysts or tumors that do not absorb contrast needed to make clear

x-ray images. Ultrasound is another noninvasive technique, but the low spatial resolution of the technology makes it difficult to diagnose small problems.[8] Finally, x-ray techniques using contrast injected into the ducts through an endoscope are collectively known as endoscopic retrograde cholangiopancreatography (ERCP). This approach provides excellent clarity and is useful in detecting sphincter dysfunction. While invasive, this technique allows for treatment and diagnosis to be administered in the same procedure.[9] If this treatment involves the cutting of the sphincter of Oddi, it is referred to as an endoscopic retrograde spincterotomy (ERS).

With ERCP and ERS, the procedure begins by the patient being anesthetized. A local anesthetic is applied to the throat to suppress the gag reflex. The patient is placed on an x-ray table to allow for continuous imaging of the patients GI tract. An endoscope is placed down the throat, through the stomach, and into the small intestines. Air is pumped into the GI tract to allow for easy maneuvering and imaging with the endoscope. Once the endoscope has reached the duodenum, the surgeon must locate the sphincter of Oddi A catheter is run down the length of the endoscope, and this catheter is placed through the sphincter and into the bile duct. Dye is injected through this catheter to allow for high contrast x-ray imaging. Once the dye is released, that catheter is removed and a new tool is placed in the endoscope. This new tool is either a sphincterotome for incision of the sphincter of Oddi or forceps for the removal of gallstones. Either mechanical or electrical mechanisms are used to incise the sphincter. If more contrast agent is needed, the catheters must be reinserted. [9]

Currently, the procedure requires use of an endoscope, a cannula for dye injection, a sphincterotome, an electrosurgical generator, a fluoroscopy machine, and radiographic contrast.[10] Currently, Olympus, Fujinon, and Pentax produce endoscopes.[11] Boston Scientific, Cook, Conmed, and Olympus make cannulas and cutting wires. [12] Olympus, Conmed, and Boston

scientific produce generators.[13] Philips and Siemens produce Fluoroscopy machines. [14] Multiple personnel are required for the procedure. The anesthesiologist ensures patient's gag reflex has been disabled and that they are unconscious for the duration of the procedure. The endoscopist: controls the endoscope insertion and positioning for surgeon. The surgeon performs cutting of sphincters, cannulation, stent placement, etc. Nurses assist in feeding endoscope and sphincterotome wires into the endoscope as well as monitoring patient vitals. Current studies have found the cost of the ERCP procedure ranges from 1,952 to 2,790 USD.[15],[16]

The effectiveness of ERCP in confirming a patient's diagnosis cannot be understated. In one study covering 1341 procedures, the accuracy of diagnosis greatly increased after performing this technique. Prior to the procedure, the physician's diagnosis was correct only 64% of the time for bile duct stones, 86-89% for other biliary dysfunctions, 77% for chronic pancreatitis, and 74% for pancreatic cancer based on observed symptoms of first time cases (849 in all). In 35% of the cases studied, the diagnostic confidence improved significantly after ERCP was performed. Using these more accurate diagnoses, additional invasive surgical procedures were reevaluated and the course of action changed in 82% of cases that required it. For example, percutaneous biliary studies and open surgical procedures were suggested less often in favor of laparoscopic techniques. This can be attributed to more precise diagnosis and identification of the patient's issue prior to any invasive surgeries.[17] By improving diagnosis accuracy through the use of ERCP, physicians were able to determine the best course of action for the patient. Despite the current ERCP procedure being considered a safe, that does not preclude it from complications. Common complications due to surgery include: bleeding, duodenal perforation, pancreatitis or cholangitis among other infections and side effects.

In a study performed by doctors at National University Hospital in Singapore, of the 336 ERCP procedures, 33 complications were reported (9.8% of total). The group observed pancreatitis in eighteen patients, bleeding in three, cholangitis in eight, duodenal tearing in one, a choledocho-duodenal fistula in one, subcapsular liver perforation in one, and one case of developed bradycardia. There were also six fatalities in the month following the procedure, but only one is attributed to the ERCP.[18] Another, larger study of 2,347 patients undergoing a biliary sphincterotomy (including ERCP procedure), there were 229 complications (9.8%). Of these patients, 127 developed pancreatitis (ranging from mild to severe), 48 had notable bleeding, 24 developed cholangitis, eleven developed cholecystits, eight had duodenal or other perforations, and the remaining 25 complications varied in cause (6 or less cases of each). Within this subset of patients, 10 died either directly or indirectly within 30 days of the procedure. According to the authors of the study, many of the injuries sustained by the pancreas were a result of cannulation of the bile ducts rather than the sphincterotomy.[19] A duodenal perforation study performed at the Los Angeles County/University of Southern California Medical Center documented 1,413 ERCP procedures. Of the 1,413, fourteen patients suffered from a duodenal perforation related to the ERCP with one case being fatal. The injuries were suspected to have been caused by the sphincterotome (6 injuries) and the endoscope/guidewire apparatus (remaining 8 injuries).[20] These studies, among others, demonstrate the most common risks involved with the current procedure for diagnosing dysfunction of the bile ducts. Overall, between 5% and 10% of all ERCP procedures result in mild to severe complications with an overall mortality rate of 1-3%.

3. Problem Statement

The main problem with current ERCP procedures is the time wasted by switching of cannulas. Under current practices, after each part of the protocol, the cannula is switched to

move on in the procedure. For example, after injecting contrast dye into the area, the clinicians must remove the dye injection tube and insert the cutting tool, extending the time of the procedure in the process. The extended period in which the patient is under anesthesia is an unnecessary stress on that patient. In addition to this, physicians lack control over the cannula once it exits the distal end of the endoscope. This means that the physician has to physically adjust the endoscope or reinsert the cannula. The most common post surgery complication, pancreatitis, is partially stimulated by continued irritation to the area caused by the extended surgical time. In addition, these continuous adjustments increase the chance of accidental perforations of the duodenum or bile duct. Studies have found that these types of complications are strongly related to skill of the endoscopist. Fewer complications arose in hospitals that performed more endoscopic procedures and those with more qualified endscopists. The overall decrease in complications in skilled medical centers was 8.4 percent versus 11.1 percent is unskilled centers.[19]

4. Need Statement

The goal of a new sphincterotome device is to remove the time spent switching tools during an ERCP procedure in order to reduce stress on the patient and the incidence of surgical complications. In addition, the apparatus should give the physician greater control over the tip of the cannula, allowing for more precise cutting and cannulation. The quantitative results of this change would be a reduced surgical time and reduced incidences of accidental damage to the surrounding area. This would manifest as a reduction of the overall incidences of complications after surgery, falling below 8.4 percent. In addition, the increased control over the cannula should result in a reduction in the divide between skilled and unskilled endoscopists.

5. Preliminary Design Concepts

There are several clinical requirements that are necessary to improve the current art in performing endoscopic cannulation, papillotomy, and sphincterotomy. Current practices use multiple cannulas to first inject the contrast dye, then cut using a conductive wire, and finally remove the obstruction. In addition, current practices involve moving the endoscope to get correct placement of the cutting wire and guide wire to the desired location. There are many variations in patients with respect to the physical anatomy, which results in difficulty to accurately and consistently place the contrast agent and cutting wires. The clinical requirements of the proposed sphincterotome are that the distal end and cutting wire be controllable without the need to move the entire endoscope. This will allow for proper placement without moving the endoscope, reducing the possibility of displacement forces on the guide wire or catheters. The other requirement is that there be one cannula in place containing the contrast agent, guide wire, and cutting wire, instead of needing to insert multiple cannulas that each contain either the contrast dye, guide wire, or cutting wire.

A possible design to satisfy the clinical requirements is to have a multi-lumen system within a single catheter that can be controlled by the handle. One lumen will then be used to carry the contrast dye to the correct location, another lumen will carry the guide wire, and a third lumen will contain the cutting wire that is connected to the handle. The handle will have the ability to rotate in order to move the cutting wire left and right, as well as a lever to pull on in order to bend the cutting wire up and down. The handle will have a locking mechanism to keep the cutting wire in the correct position as the physician's discretion.

An alternative proposed sphincterotome would have a steerable sphincterotome that allows the physician to have control over the distal tip to adjust for any inconsistencies in anatomy or endoscope positioning, similar to the previous proposed design. In addition, the

proposed sphincterotome will be an improvement over the current art in that the guide wire, cutting wire, and contrast agent can all be used within one lumen, removing the extra step of inserting multiple cannulas and needing to position them multiple times. This is an added feature over the previous proposed solution in that all the proximal lumens will converge into one distal lumen, reducing the size of the cannula. Through the proximal lumens, a guide wire, contrast dye, and a cutting wire can each be inserted into the cannula. The ergonomic handle will allow for physician comfort and the independent control over the position of the distal end and cutting wire. The locking mechanism of the handle will secure the position of the distal end, ensuring proper placement throughout the entire procedure.

The main risk of the proposed solution is in regards to the cutting wire. If the cutting wire is not properly placed through the distal end of the sphincterotome, there is a possibility of short-circuiting and excessive heat generation. In this scenario, the cutting wire can contact the endoscope if it is not properly placed. This will cause a short-circuit and an increase in heat through the distal end of the cutting wire. The cutting wire can become hot enough to sever itself and become dislodged within the patient, as well as get hot enough to cause burning in the patient. However, having a properly coated guide wire in place during the procedure can alleviate the possibility of patient burning.[21]

The benefits of the proposed solutions are numerous. The first is that the distal end of the sphincterotome is controllable by the physician without having to move the endoscope. The proposed handle is ergonomic and comfortable for the operator. In addition, it can be used to rotate the distal end, as well as bend it into the proper location. The handle will have a locking mechanism that will keep it securely in place. There is a problem in previous procedures in which during unattended periods, the cutting instrument will begin to relax and bow, moving to

an unwanted orientation that will then need to be corrected for once again.[22] The locking handle removes this problem because it will be maintained in the proper orientation regardless of the unattended time duration. An additional benefit is that the proposed sphincterotome is multi-lumen and will require less cannula exchanges. Often times, during the catheter exchanges, the guide wire becomes displaced and it will need to be redirected through the body ducts, which is a very difficult procedure and increases the time of the operation. The proposed solutions will allow for a faster procedure with fewer components, reducing patient trauma and overall time and cost.

The final product will address the need of reducing the time spent during the procedure, reducing the amount of time the patient is under anesthesia. This is done by including the contrast dye, cutting wire, and guide wire into one cannula, and removing the need to switch between cannulas. In addition, the proposed final product will give the physician control over the cannula tip, allowing for more precise cutting and cannulation. The single cannula inserted will cause lower incidents of pancreatitis caused by accidental perforations of the duodenum or bile duct, which occurs during multiple insertions of cannula. [20] Also, once the distal end is properly located, it can remain in place throughout the procedure and other surgical devices can be placed onto the guide wire, increasing precision and reducing the occurrences of accidental perforations.

The handle has the ability to control the distal end and orientate the cutting wire. The proposed design will eliminate the step of requiring a precut in order to place the cutting wire into place, where it will then cut a larger hole.[23] The cutting wire is the necessary component that the rest of the procedure is dependent on and a failure of the cutting wire will result in the failure of the procedure. The demonstration of the cutting wire to withstand the tension and torsional forces imposed by the turning of the handle is required to show feasibility. The

feasibility of the proposed device will be demonstrated by the tensile and torsional characterization of the material used in the cutting wire. The proposed handle will therefore be restricted in the torsion and tensional forces imposed as to not exceed the strength of the cutting wire material.

Assignment 2 (No Regrade)

6. Statement of Intended Use

The Hydratome RX 44 Sphincterotome is a multi-cannula system that can be used during transendoscopic sphincterotomies in the biliary duct and pancreatic ducts, specifically the Papilla of Vater and/or the Sphincter of Oddi. This device allows for a guiding wire, a contrast agent lumen, and a cutting wire to be guided simultaneously down an endoscope tube to the biliary ducts. Once there, the device can assist with imaging, cannulation, and cutting of the sphincters of the biliary duct.[24] [25]

7. Statement of Indication of Use

The Hydratome RX is indicated for the use of transendocopic cannulation, dye injection, and sphincterotomy of the Papilla of Vater and the Sphincter of Oddi. [26]

8. Functional & Performance Specifications

The Hydratome RX44 must perform several functions to meet the needs of the device. First, the device must treat conditions caused by inflammation or constriction of the biliary duct. To accomplish this, the sphincterotome must be able to reach the papilla of Vater and the sphincter of Oddi, which are located in the duodenum. Thus, the catheter used to perform exploratory or therapeutic surgery must be 200cm to reach the biliary duct. Additionally, the guidewire must be at longer than the catheter; a length of 260cm would suffice. The guidewire will come preloaded into the device to prevent contamination or human error. The device must also be able to perform a sphincterotomy if necessary and must therefore have a cutting tip. The cutting wire is 20mm or 30mm depending on the patient and surgery needs; it also uses an electric current to cut the tissue while also cauterizing it, which is powered through the handle. The maximum voltage to be run through the wire will be 1.5kV to ensure that the device cuts, but does not produce excessive risk to the patient.

Second, the device must be able to cannulate the biliary duct. The guidewire must be able to carry the cannula to the proper location and release it. This includes the device fitting into the biliary duct and the sphincter (about 6mm in diameter)[27]. The cannula must then be expelled from the lumen using the guidewire to slide it into position. Additionally, the device tip must articulate to properly place the cannula, which can be achieved by rotating the handle. It will need to rotate at least 40º to gain access to the average biliary duct.[28] [29] The device must withstand 15 Nm of torque to assure the device can easily be operated by hand without failure. The rotation will not be limited, however, such that the device can be rotated continuously if need be.

Finally, the Hydratome must be able to inject x-ray imaging contrast agent into an area of interest during surgery. To accomplish this, a third lumen (in addition to the guidewire and cutting wire lumens) must be used to isolate the dye from the other wires. This lumen must also run the length of the catheter to allow injection of contrast agent from an external source. This lumen will be connected to an injection port on the handle. The device will need to be able to dispense 4 mL of contrast agent.[30] With regards to control, the device must dispense no more or less than 0.1 mL than what the surgeon intended.

9. Test Plan

1. The device must treat conditions caused by inflammation or constriction of the biliary duct

To verify the performance specifications under this functional specification, quantitative measurements of the device must be taken. After manufacturing, the guidewire and catheter will be measured. In particular, the catheter must be 200cm long, the guidewire must be 260cm long, and the width of the cutting wire must be 20cm or 30cm. Finally, a voltmeter will be used to ensure the voltage output of the cutting wire meets specifications. This output must be 1.5 kVolts to allow for adequate cutting of the soft tissue.

After verification, the functional specification of the catheter, guidewire, and cutting wire must be validated. This will be tested in animal models to insure that the length and width of each component can be reliably fed through the animal's digestive system to the Papilla of Vater. At this point, the cutting wire will be validated by ensuring that application of voltage will effectively cut through the Spincter of Oddi allowing for further treatment of biliary duct disease.

2. The device must be able to cannulate the biliary duct

To verify the performance specifications of this functional specification, the rotation of the guidewire and ability to deliver cannulate the biliary ducts will be tested. The guidewire will be put through rotation and force testing to ensure the design meets the expected 40º and 15 Nm to maneuver a cannula into the biliary duct. The cannula must be measured to verify the 2.33mm diameter required for cannulation.

After verification, the functional specification of the cannula and guide wire must be validated. To achieve this, an animal model will be tested to ensure the ability of the device components to reliably cannulate the biliary duct.

3. Hydratome must be able to inject x-ray imaging contrast agent into an area of interest during surgery.

To verify the performance specifications of this functional specification, an analysis of the reliable delivery of contrasting agent will be performed. In particular, a volumetric analysis of the contrast agent will be determined to verify that 4 mL of contrasting agent can be delivery through the lumen of the device. The lumen will need to be tested for pressure tolerances so that 0.1 mL delivered over 5 seconds will not cause failure in the tubing.

10. Product Design Concept

There are several major components that all come together to make the entire handle of the Hydratome RX 44. The first is the center handle itself, which can be seen in appendix

A. This handle holds the slider (appendix B) and allows for the control of the rotation of the distal tip. The slider contains the electrical connection to draw electricity through to the cutting wire, as well as a connection to the distal tip that allows for the angulation of the cutting wire. The handle then connects to the contrast injection site (appendix C), which tapers the size of the handle into the connection (appendix D) with the cutting wire injection site (appendix E). Finally, the cannula (appendix F) that will hold the cutting wire and guide wire comes out of the cutting wire injection site. The configuration of the Hydratome RX 44 can be seen in the exploded view of figure 1. The entire proximal handle (shown in green in figure 1) is made from plastic, except for the electrical connection site and guide wire connection piece of the slider. The black connection piece shown in figure 1 is rubber, while the distal tube is made of clear plastic.

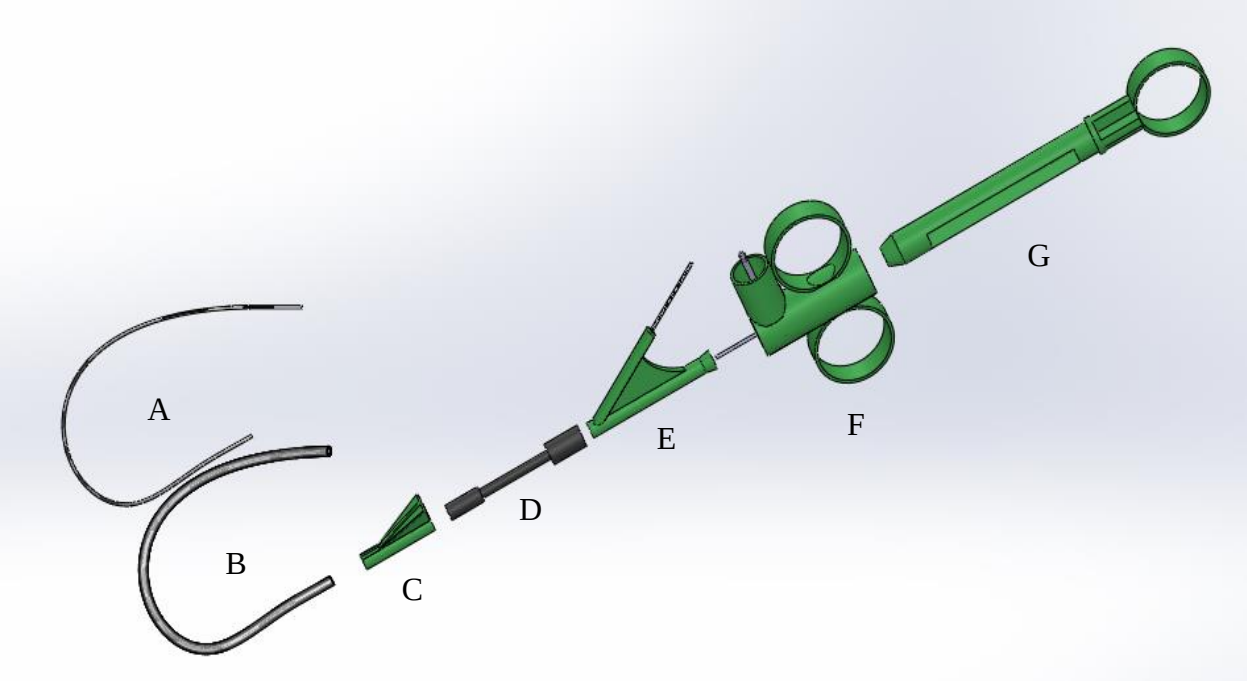

Figure 1: Exploded view of the proposed Hydratome RX 44 device showing each individual component. (A) Hydra Jagwire Guidewire (cutting wire) (B) Cannula (C) Cutting Wire Injection Site (D) Connector (E) Contrast Agent Injection Site (F) Slider (G) Handle

The packaging of the device will be in a sterile bag because of the fact that this device will be entering the body. The surgeon will be able to open the packaging and remove the device in an easy to open manner. The labeling on the device will contain the manufacturer of the device as well as the name of the device in large letters to ensure the correct choice of the device while in the operating room. There will also be a contents list that will contain the components of the device that is inside the packaging, and a clearly labeled diagram of guide wire and cutting wire. There will be the manufacturers address and contact information also on the front of the packaging with the lot number and reference numbers of each component that is present in the packaging. On the reverse side of the packaging will be the user manual that contains warnings, device description, indications for use, adverse events, precautions, preparation instructions, and directions for use.

Assignment 3

11. Intellectual Property Review

Our product has several key patents which make it both highly functional and unique for endoscopic procedures. First, the method with which the device delivers the cutting wire and contrast agent requires two lumens embedded within a rapid exchange catheter as described in patents US6007522, US6606515, and US6879854 (filed in 1997, 1999, 2003 respectively). The two lumens within the catheter are complimented by a third U-shaped lumen which houses the guidewire and allows for rapid catheter exchange along its length. This platform allows for a single operator (two if available) to quickly exchange devices along the length of the guidewire. These patents also describe a design and method for inserting the guidewire through an external funnel-shaped port which connects directly to the catheter's guidewire lumen; this port gives ease of insertion as well as a specialized notch where the clinician can place the guidewire to fix it in place when the target is reached. These patents are central to the general design of the device and allow for a single device to complete a surgery instead of several. These patents were used in predicate devices to the Hydratome RX44, but several were filed for this device. For example, patent US7706861 describes a more modern version of this technology with an improved notch to hold the guidewire as well as a reshaped funnel. Additionally, several more recent patents were filed for the specialized handle used in our device. The handle consists of a rotatable portion which can be turned to articulate the tip of the cutting wire without rotating the catheter as well as multiple ports for inserting 1) the guidewire, 2) the cutting wire, and 3) and the contrast agent. The patents which describe this (as well as the mode of operation for the device) are: US6676659, US6827718, and US7371237. Thusly, they describe: that the handle will have a locking mechanism to hold the tip in the prescribed orientation to allow a single operator to perform the procedure needed, that the handle will be inhibited from rotating past a certain point,

that there are visual markings which delineate the rotation of the tip and handle, and that the device will use an electrosurgical tool (cutting wire) to perform any enlargement surgeries (cutting). These innovations are important for the proper positioning and control which is needed to complete sphincterotomy and other biliary-related procedures. Finally, patent US7645254 describes the actual method of using the device to inject contrast agent into the desired area to facilitate more precise imaging. This is vital for the reduction of difficulty and increasing the success of surgery.

12. Regulatory Classification

Given the use of electrosurgical equipment in in the GI tract, the Hydratome RX 44 is a KNS product, as described by the FDA.[31] Such products are "Endoscopic Electrosurgical unit and accessories". Devices in this category are classified as Class II devices, requiring a 510(k) for approval. Boston Scientific's own Autotome exists as predicate device.[32] In accordance with FDA regulations stated in 21CFR876.4300[33] these devices must adhere to specified performance standards in their 510(k). Premarket review of this 510(k) is expected to be performed by the Office of Device Evaluation, the Division of Reproductive, Gastro-renal, and Urological Devices, and the Urology and Lithotripsy Devices Branch.

13. Regulatory Notification / Approval

Section 5
510(k) SUMMARY

510(k) SUMMARY
1. Submitter:

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Contact: Ryan Grubbs
Regulatory Affairs Specialist
Date Prepared: September 10, 2009

2. Proposed Device:

Trade Name: Hydratome™ RX Sphincterotome,
Classification Name: Endoscopic Electrosurgical Unit and Accessories
Regulation Number: 876.4300
Product Code: KNS
Classification: Class II

3. Predicate Devices:

Trade Name: Autotome ™ RX Sphincterotome
Manufacturer and Clearance Number: Boston Scientific Corporation, K013153
Classification Name: Endoscopic Electrosurgical Unit and Accessories
Regulation Number: 876.4300
Product Code: KNS
Classification: Class II

Trade Name: Ultratome ™ XL Sphincterotome
Manufacturer and Clearance Number: Boston Scientific Corporation, K930022
Classification Name: Endoscopic Electrosurgical Unit and Accessories
Regulation Number: 876.4300
Product Code: FDI
Classification: Class II

4. Proposed Device Description:
The proposed Hydratome™ RX is a triple lumen sphincterotome with controlled orientation and rotation features. It is compatible with the Boston Scientific Microinvasive Endoscopes Rapid Exchange™ platform and can accommodate a 0.035" guidewire while allowing simultaneous injection through a separate lumen.

5. Indication for Use:
The Hydratome RX Sphincterotome is a multi-cannula system that can be used during transendoscopic sphincterotomies in the biliary duct and pancreatic ducts, specifically the Papilla of Vader and/or the Sphincter of Oddi. This device allows for a guiding wire, a contrast agent lumen, and a cutting wire to all be guided simultaneously down an endoscope tube to the biliary ducts. Once there, the device can assist with imaging, cannulation, and cutting of the sphincters of the biliary duct.

6. Technological Characteristics:
The proposed Hydratome™ Sphincterotomes are similar in design, materials, and manufacturing processes to the predicate, Autotome ™ RX Sphincterotome (K013153) and Ultratome ™ XL Sphincterotome (K930022).

7. Performance Data:
The proposed device is substantially equivalent to the currently marketed Rapid Exchange™ Cannulating Sphincterotome in terms of performance characteristics tested and biocompatibility.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the Hydratome™ RX Sphincterotome is substantially equivalent to the predicate device Autotome™ RX Sphincterotome (K013153). Therefore the proposed Hydratome™ RX Sphincterotome is as safe and as effective as the predicate device.

14. FMEA

Item (Figure 1 Label)	Function	Failure Mode	Potential Effects of Failure	Severity	Occurrence	Detection	Causes	RPN	Actions	Responsibility /Deliverable
Cutting Wire (A)	• Cauterize the papilla	• Increase heat production and melting • Doesn't perform proper cauterization	• The wire can severe and dislodge in the patient • Too much current can lead to burns • Too little current will not properly cauterize	9	2	8	• Improper current setting by doctor • Improper insulation from other pieces of the Hydratome	144	• Have a relay that trips when too much current is detected	R. Attardo/ January 20, 2014
Cannula (B)	• Holds the cutting wire, contrast, and guidewire in one lumen	• Cracking • Bending • Obstruction	• Loses sterility when cracks occur • Kinks inhibit proper use • Cutting wire and contrast can't reach correct location	1	2	1	• Mishandling of the device • Foreign materials enter through contrast and cutting wire injection sites	2	• Design caps that will cover the contrast agent and cutting wire injection sites	T. Gunnels/ February 2, 2014
Cutting Wire Injection Site (C)	• Provides an opening for insertion and removal of the cutting wire	• Obstruction • Doesn't properly hold the cutting wire in place during the procedure	• Cutting wire will need to be removed and reinserted	4	1	1	• Foreign material enters into the injection site • Open slit causes the cutting wire to move inside the cannula	4	• Develop a cap for the cutting wire injection site • Removal of slit in device design • Add locking mechanism for cutting wire to hold in place	A. Ravilla/ February 2, 2014

Connector (D)	• Connects contrast and guidewire lumens to one lumen in the cannula	• Cracking and general damage	• Contrast won't reach correct location	1	1	1	• Improper manufacturing or handling	1	• None - Found during manufacturing and inspection	
Contrast Agent Injection Site (E)	• Location for contrast agent to be inserted	• Contrast syringe isn't correct size for injection site	• Contrast won't reach correct location	1	1	1	• Incorrect choice of syringe size	1	• Use a different syringe with correct size	Doctor/ During procedure
Slider (F)	• Electrical connection for cutting wire • Controls distal tip location	• Loses control of distal end	• Procedure must be stopped because the cutting wire can't be properly placed	5	3	9	• Guidewire becomes severed	135	• Add an additional guidewire attachment incase of failure of the first	R. Grubbs/ January 20, 2014
Handle (G)	• Guides the slider • Controls rotation of distal tip	• Cracks or fatigue • Detaches from rest of assembly	• Procedure must be stopped • Lose the fixed position of distal tip	1	1	1	• Improper manufacturing or handling	1	• None – Found during manufacturing and inspection	

15. Preclinical and Human Study Plan

Preclinical testing will be used to validate the device's functional specifications *in vivo*. We will use a pig analog to confirm that the device can reliably cut the Sphincter of Oddi and cannulate the biliary ducts for the treatment of biliary diseases.

A pig model will be used because of the similarity in digestive anatomy and relative size of the digestive tract. The device will be tested by feeding the sphincterotome down the pig's digestive tract into the Papilla of Vater. Here, the rotation of the guide wire will be tested as detailed in the test plan, checking for degree of rotation. The Sphincter of Oddi will be cut to ensure the cutting wire functions in the aqueous environment of the body. Finally, the biliary duct will be cannulated to confirm that capability of the device to treat a variety of biliary diseases, including those that require cannulation. These animal trials will confirm our device is safe and effective for our indications for use. All regulations in the following documents will be followed: IEC 60601-1, ISO 14971:2007, ISO 10993, ISO 11135-1: 2003, and ASTM F1 980-07: 2007. Furthermore, an IRB approval will be required before these preclinical studies are conducted.

Human clinical trials will not be necessary, as detailed in our premarket notification. We believe that there is not a significant difference between our device and predicate devices in terms of safety and efficacy. Therefore, human clinical trials will not be required for this device.

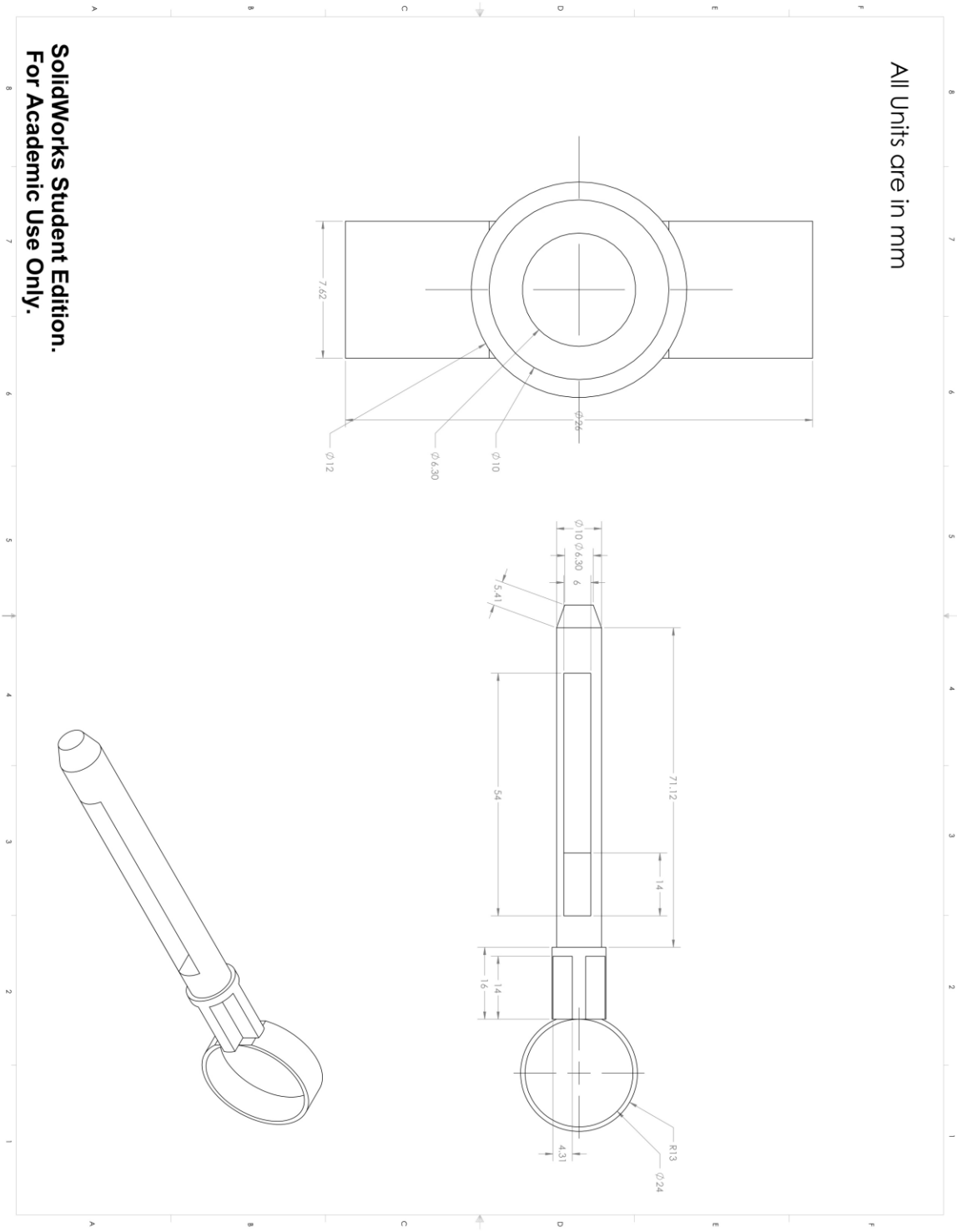
16. Standards and Guidelines

To insure an expedited approval process, improved patient safety, and general good manufacturing practices, several standards will be adhered to. The International Electrotechincal Commission (IEC) has a set of standards for "Medical Electrical Equipment" specifically "Particular Requirements for the Safety of High Frequency Surgical Equipment".[34] The

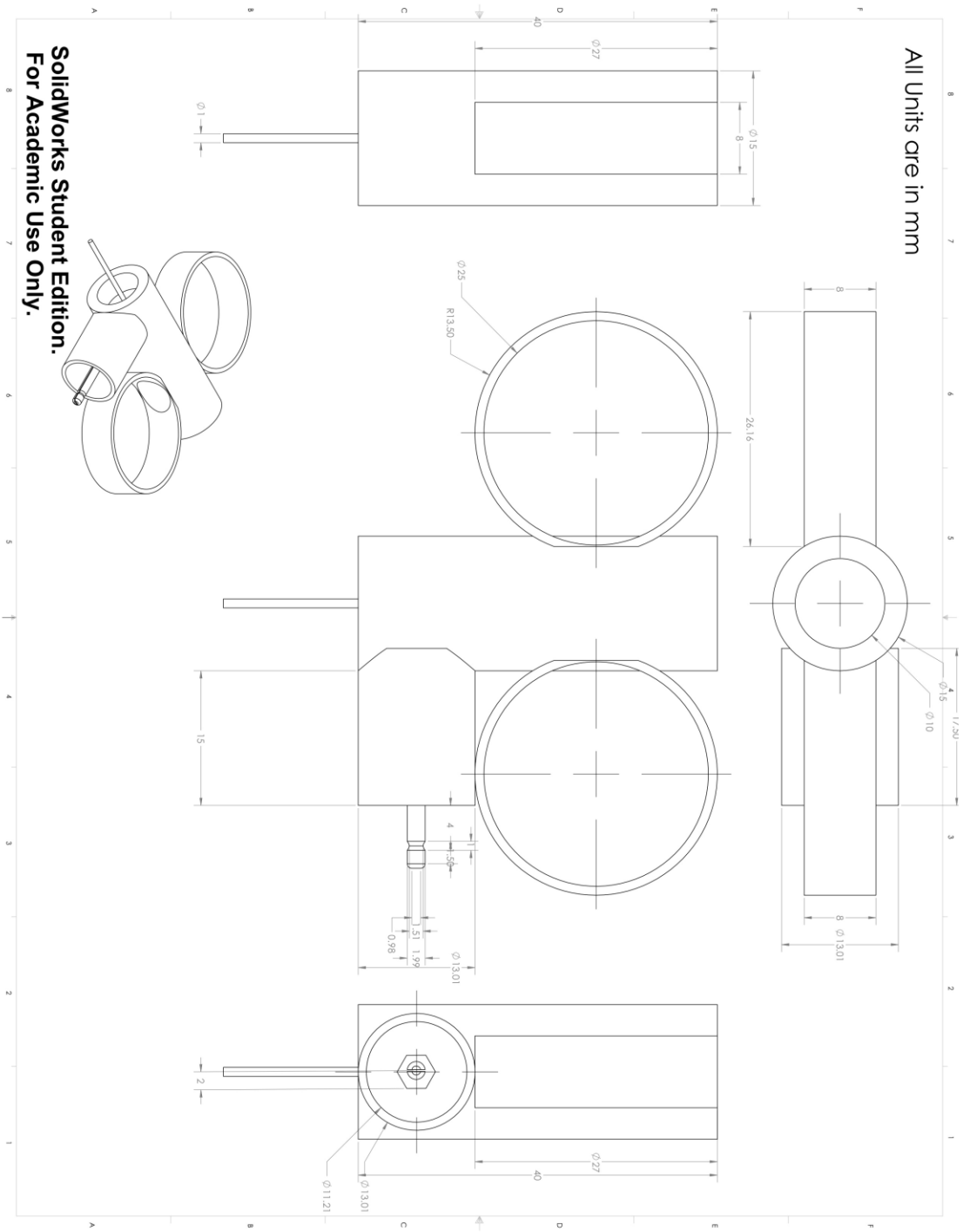
Hydratome depends on the delivery of high current through its cutting wire, thus adhering to these standards reduces potential harm. Moreover, as our device is an accessory to an endoscope, standards detailed by the American Society for Testing and Materials (ASTM): "Standard Practice For Reprocessing Of Reusable, Heat-Stable Endoscopic Accessory Instruments (Eai) Used With Flexible Endoscopes. (ObGyn/Gastroenterology)".[35] Due to the high chance of infection if our device were to be reused, the Hydratome is designed as a single-use device.[36] Together, these two standards should ensure maximum patient safety.

Appendix

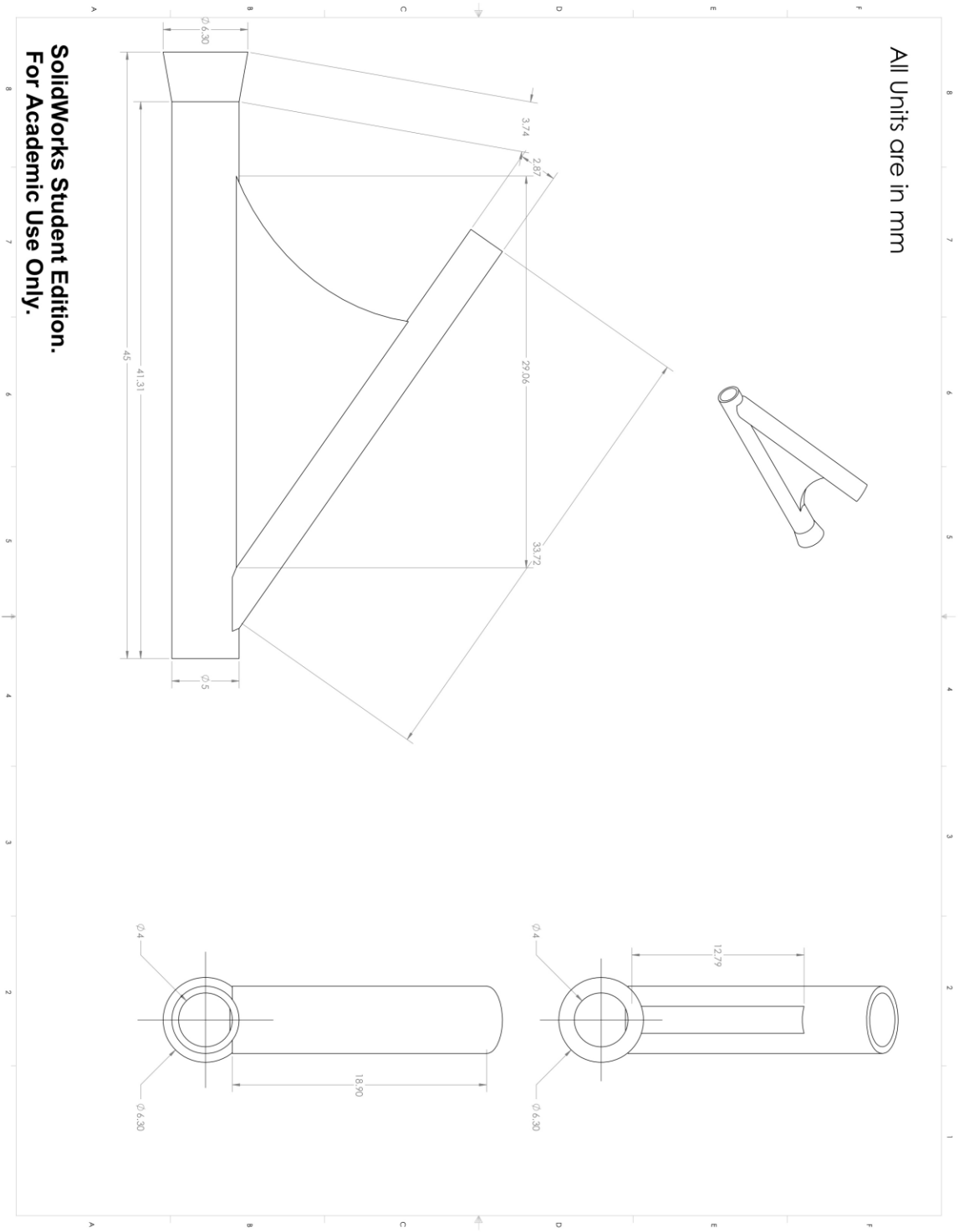
A. Handle



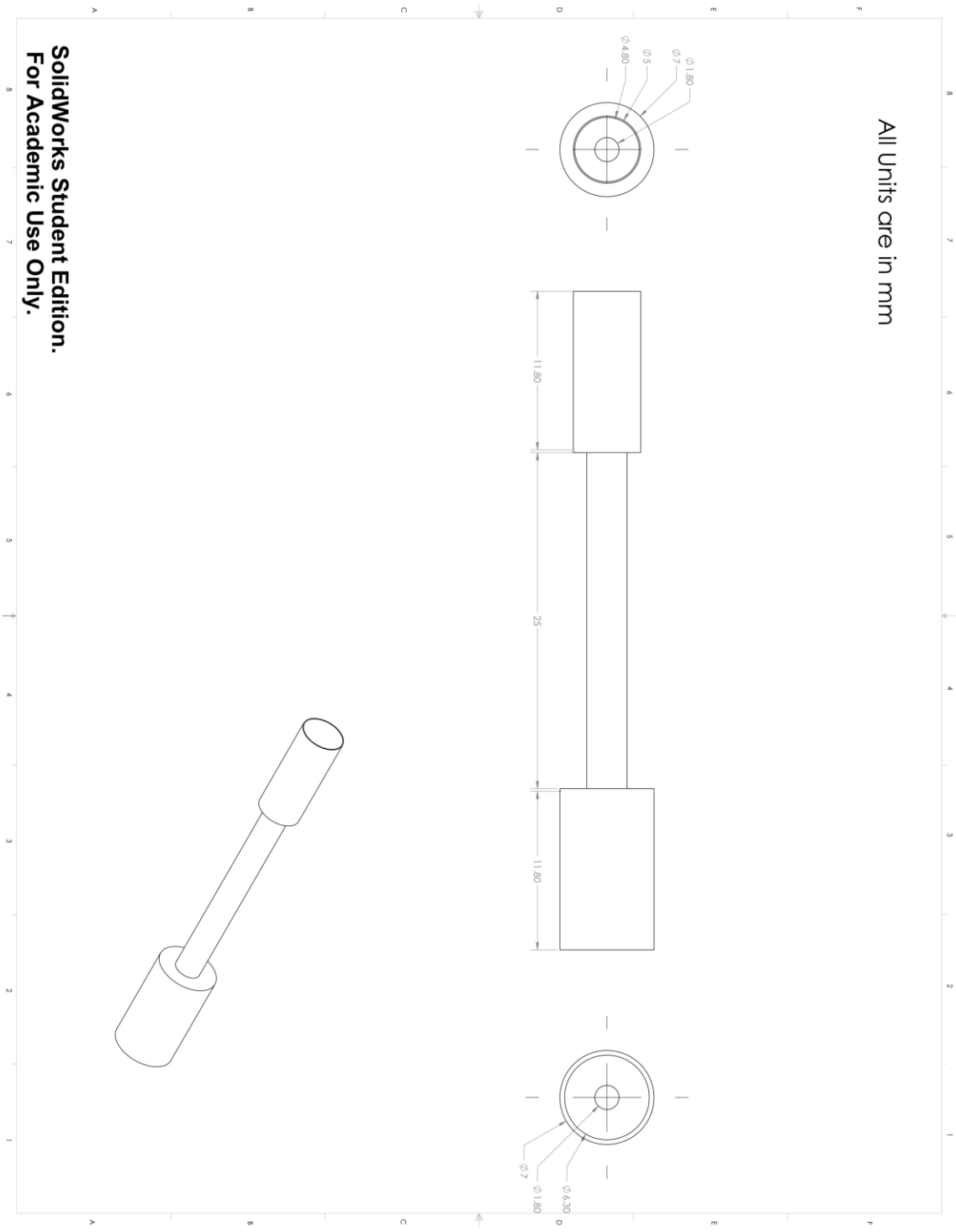
B. Slider


All Units are in mm
SolidWorks Student Edition.
For Academic Use Only.
40
Ø27
Ø1
Ø15
8
Ø25
R13.50
26.16
Ø10
15
4
1.50
1.51
0.98
1.99
Ø13.01
2
Ø11.21

C. Contrast Agent Injection Site



D. Connector


All Units are in mm
SolidWorks Student Edition.
For Academic Use Only.
Ø4.80
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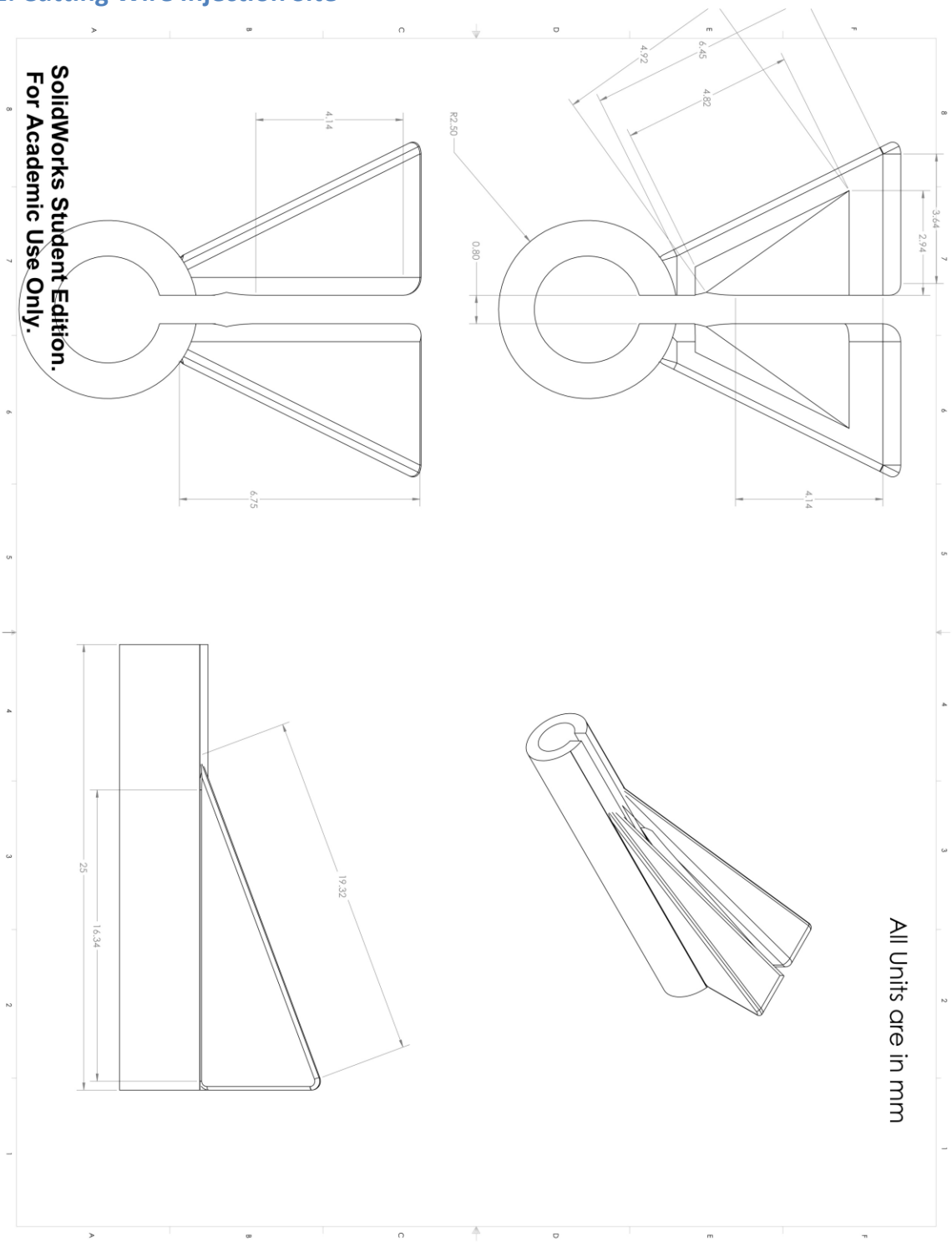
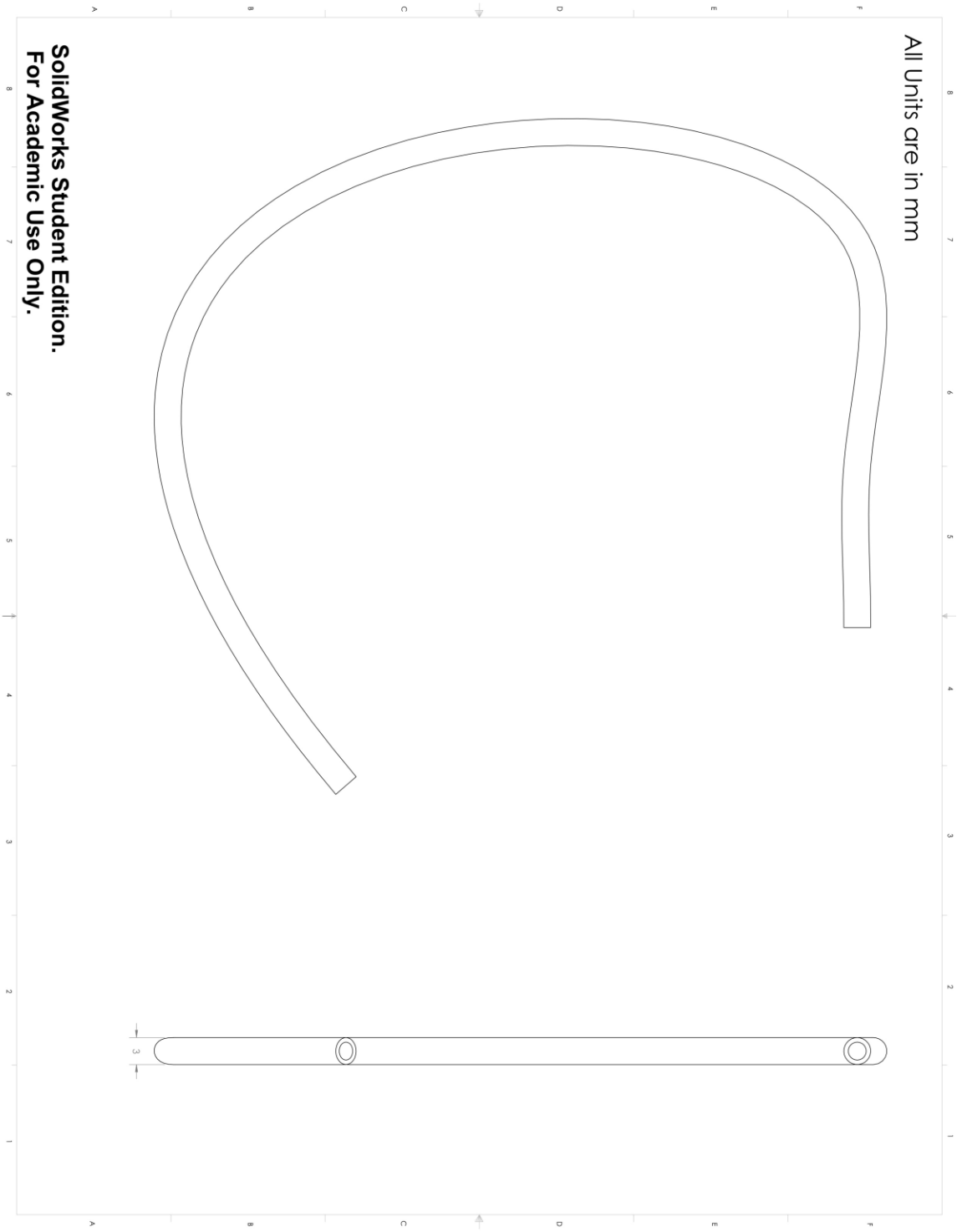
11.80
25
11.80
Ø7
Ø1.80
Ø6.30

E. Cutting Wire Injection Site



F. Cannula


All Units are in mm
SolidWorks Student Edition.
For Academic Use Only.

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